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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,166	08/07/2006	Valerio Berdini	3073.004A	7842

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EXAMINER	
STOCKTON, LAURA LYNNE	
ART UNIT	PAPER NUMBER
1626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,166	BERDINI ET AL.	
	Examiner	Art Unit	
	Laura L. Stockton, Ph.D.	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *57-99* is/are pending in the application.

4a) Of the above claim(s) *57-71,86-95,97 and 98* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *72-85,96 and 99* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 57-99 are pending in the application.

Election/Restrictions

Applicant's election without traverse of Group V (Claims 72-85 and 96 - drawn to products of formula IV, formula V, formula VI, formula VII and formula VIIa) in the reply filed on September 15, 2009 was acknowledged in the previous Office Action. The requirement was deemed proper and therefore made FINAL in the previous Office Action.

Claims 57-71, 86-95, 97 and 98 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on September 15, 2009.

Rejections and objections made in the previous Office Action that do not appear below have been overcome by Applicant's amendments to the specification and claims. Therefore, arguments pertaining to these objections and objections will not be addressed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 72-85, 96 and 99 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a salt or N-oxide of the compounds, does not reasonably provide enablement for a solvate of the compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to

make the invention commensurate in scope with these claims.

Factors to be considered in making an enablement rejection are summarized as:

a) the quantity of experimentation necessary,

b) the amount of direction or guidance presented,

c) the presence or absence of working examples,

d) the nature of the invention,

e) the state of the prior art,

f) the relative skill of those in the art,

g) the predictability or unpredictability of the art, and

h) the breadth of the claims.

In re Colianni, 195 USPQ 150 (CCPA 1977). *In re Rainer*, et al., 146 USPQ 218 (CCPA 1965). *Ex parte Formal*, 230 USPQ 546 (BPAI 1986).

a) Determining if a particular compound would form a solvate or hydrate would require synthesis and recrystallization of the compound solvate using a

variety of solvents, temperatures and humidities. The experimentation for solvates or hydrates is potentially open-ended.

b) The specification merely mentions the Applicant's intention to make solvates, without teaching the preparation thereof.

c) While the claims recite solvates, no working examples show their formation. As stated in *Morton International Inc. v. Cardinal Chemical Co.*, 28 USPQ2d 1190, 1194 (Fed.Cir. 1993):

> The specification purports to teach, with over fifty examples, the preparation of the claimed compounds ... However ... there is no evidence that such compounds exist ... [T]he examples ... do not produce the postulated compounds ... [T]here is ... no evidence that such compounds even exist.

The specification shows no evidence of the formation and actual existence of solvates and hydrates. Hence, Applicant must show formation of solvates or limit the claims accordingly.

d) The nature of the invention is chemical synthesis of solvates, which involves chemical reactions.

e) The state of the art recognizes that the formation, composition and therapeutic activity of solvates are unpredictable. The Federal Circuit has recognized a solvate as an example of a polymorph or pseudopolymorph (emphasis added):

> "Polymorphs" are distinct crystalline structures containing the same molecules. These structural differences can affect various properties of the crystals, such as melting points and hardness (e.g., graphite and diamonds are both crystalline forms of carbon) .... [P]seudopolymorphs are often loosely called polymorphs ... Pseudopolymorphs not only have their molecules arranged differently but also have a slightly different molecular composition. A common type of pseudopolymorph is a solvate, which is a crystal in which the molecules defining the crystal structure "trap" molecules of a solvent. The crystal molecules and the solvent molecules then bond to form an altered crystalline structure.

SmithKline Beecham Corp. v. Apotex Corp., 74 USPQ2d 1398, 1409 (Fed.Cir. 2005). The same rationale obtains

for hydrates; solvates in which the solvent is water. Souillac, et al., Characterization of Delivery Systems, Differential Scanning Calorimetry, pages 217-218 (in Encyclopedia of Controlled Drug Delivery, 1999, John Wiley & Sons, pages 212-227), recognize that different polymorphs of the same drug can have different therapeutic activity (emphasis added):

> Because different polymorphic forms of the same drug exhibit significant differences in their physical characteristics, therapeutic activity from one form to another may be different. Studying the polymorphism of a drug and the relative stability of the different polymorphs is a critical part of pre-formulation development.

Further, Vippagunta et al. (Advanced Drug Delivery Reviews, 48 (2001), pages 3-26) state "Predicting the formation of solvates or hydrates of a compound and the number of molecules of water or solvent incorporated in to the crystal lattice of a compound is complex and difficult." See page 18, section 3.4.

f) The artisan using Applicant's disclosure to prepare the claimed solvates would be, e.g., an

experienced process chemist with at least a BS chemistry degree.

g) Chemical reactions are known as unpredictable. *In re Marzocchi, et al.*, 169 USPQ 367, 370 (CCPA 1971); *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970). See above regarding the unpredictability of solvate formation.

h) The breadth of the claims includes thousands of compounds of the instant formulas as well as presently unknown compounds embraced by the terms solvates. See MPEP 2164.01(a), discussed supra, justifying the conclusion of lack of enablement commensurate with the claims. Undue experimentation will be required to practice Applicant's claimed invention.

Response to Arguments

Applicant's arguments filed March 25, 2010 have been fully considered but they are not persuasive. Applicant argues that: (1) whether or not a compound is in the form of a crystalline solvate is essentially

immaterial to the biological activity of the compounds and that solvates are well known in pharmaceutical chemistry; (2) the present invention does not require undue experimentation for the skilled artisan; (3) the presence or absence of working examples is not indicative of the enablement of pending claims; (4) a copending application (11/813,031) discloses a hydrate of a compound which is embraced by the instant claimed compounds; and (5) various US patents have been granted with claims that include solvates.

All of Applicant's arguments have been considered but have not been found persuasive. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and thus use the invention commensurate in scope with the instant claims. Applicant's traverse to this rejection is not persuasive for the following reasons. The Examiner has stated the reason for the rejection is based on evidence in Applicant's own

specification of many examples which consistently failed to produce solvated forms, other than a hydrate of a compound in a copending application. While it may be routine to make solvates by exposing compounds to a variety of solvents, this does not mean it is routine for any given compound to form solvates - a fact clearly stated by Vippagunta. As was stated in *Morton International Inc v. Cardinal Chemical Co.* 28 USPQ2d 1190 at page 1194: "The specification purports to teach with over fifty examples, the preparation of the claimed compounds with the required connectivity. However… there is no evidence that such compounds exist… the examples of the '881 patent do not produce the postulated compounds..there is… no evidence that such compounds even exist." . The same applies in the instant case. Note that in *University of Rochester v. G.D.Searle & CO.* 68 USPQ2d 1424 at 1438 the screening for over 600 compounds was deemed to be undue.

Applicant's claimed scope of compounds far exceeds this number.

Applicant urges what is best known can be omitted but the fact remains reacting the instant claimed compounds in various solvents, which is the known way to ultimately make solvates, failed to produce solvates, other than a hydrate of a compound in a copending application wherein the solvent is water. If it is so routine as Applicant argues, then why aren't any of the 300+ compounds made in the various working examples employing a variety of solvents? The lack of such supports Vippagunta's assertion that it is not predictable which compounds can form solvates. Thus, there is ample evidence to doubt the existence of such compounds for instant compounds. *In re Marzocchi* 169 USPQ 367. Note MPEP 2164.08(b) which states that claims that read on "... significant numbers of inoperative embodiments would render claims nonenabled when the specification does not clearly identify the operative

embodiments and undue experimentation is involved in determining those that are operative." . Further, considerations and determinations of patentability of claims in U.S. patents has no relevancy in the consideration and determination of patentability of claims in the instant application. See the rationale given in *In re Greider et al.*, 54 U.S.P.Q. 139 (CCPA 1942). For all the reasons given above, Applicant's arguments are not persuasive. The rejection is deemed proper and therefore, the rejection is maintained.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 72-85, 96 and 99 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim

the subject matter which applicant regards as the invention.

In claim 72, under the definition of variables R^b and R^{1a}, "groups" should be singularized since there is only one R^b and one R^{1a} variable. For example, under R^{1a}, a 6-membered monocyclic aryl group; a 6-membered monocyclic heteroaryl group, etc. See claims 73, 77, 78 for same.

In claim 73, an "or" should be added before the phrase "(ii) when R^{1b} bears 2, 3 or 4 substituents".

In claim 73, the phrase "or two adjacent substituents together with the carbon atoms to which … heteroatoms selected from N, O and S;" (found in the 2nd through the 5th lines from the end of claim 73) lacks antecedent basis from claim 72.

In claims 74 and 99, the "R^{1a}-NHC(=O)" in claim 74 and the "R^{1b}-NHC(=O)" in claim 99 do not represent a **urea** in the group R^{1a}-A-NH.

In claim 78, under the definition of R^a, an "or" should be added before "$C(X^2)X^1$".

In claim 78, under the definitions (b), (c), (d) and (e), the hydrocarbyl substituted with acyloxy lacks antecedent basis from claim 72.

In claim 78, under definition (e), the phrase "R^{6a} to R^{9a} include" should be changed to "R^{6a} to R^{9a} are each".

In claim 78, under definition (e), an "and" should be added before "heterocyclic group with 3-7 ring members" at the end of the claim.

In claim 80, under the definition of variables R^{6a}, R^{9a} and R^{7a}, the phrase "R^{11} and R^{12} together with the nitrogen atom form a five or six membered heterocyclic ring" lacks antecedent basis from claim 78.

In claim 81, under definition (b), an "and" should be added before *p*-morpholino.

In claim 81, under definition (d), an "and" should be added before *p*-methoxy.

In claim 81, under definition (g), an "and" should be added before piperidinylmethyl.

In claim 81, under definition (z), "benzfuran3-yl" should be changed to "benzfuran-3-yl".

In claim 81, under the definition of variable (aa), "2-pyrimidinyl-1piperidin-4-yl" should be changed to "2-pyrimidinyl-1-piperidin-4-yl".

In claim 81, after the definition (ab), an "and" should be added.

In claim 81, under the definition of R^{9b}, an "and" should be added after morpholinosulphonyl.

Claim 83 does not conform to M.P.E.P. 608.01(m) since each claim must end with a period thereby establishing that no other subject matter is missing from the claim.

Claims 84 and 85 lack antecedent basis from claim 72 because of the definition of variable A representing a bond and variable m representing zero.

In claims 84 and 85, the R^9 variable is not defined.

Claim 99 does not further limit claim 73.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an

invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 72-85, 96 and 99 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-83, 104, 106-115 and 125-127 of copending Application No. 11/813,031. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claimed compounds are generically claimed in the copending application.

The indiscriminate selection of "some" among "many" is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (C.C.P.A. 1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., treating viral infections).

One skilled in the art would thus be motivated to prepare products embraced by the copending application to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating, for example, viral infections. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed March 25, 2010 have been fully considered. Applicant states that he will await the lifting of the provisional rejection in the instant application until the claims are otherwise in

condition for allowance. In response, any arguments presented in the future will be deemed untimely.

As stated in the previous Office Action, the comparative showing on pages 260-262 of the instant specification has been considered. However, the comparative showing on pages 260-262 is insufficient to overcome the rejection of the instant claims based upon 35 USC 103 over Edwards et al. {WO 2003/035065} as set forth below: because the showing is not commensurate in scope with the instant claims. *In re Greenfield*, 197 U.S.P.Q. 227 (1978) and *In re Lindner*, 173 U.S.P.Q. 356 (1972). Also see M.P.E.P. 716.02(d). The instant R^{1a} variable definition embraces a plethora of substituents (i.e., cycloalkyl rings; heterocyclic rings, heteroaryl rings; etc.), which substituents are also taught in

Edwards et al. Therefore, the showing is not persuasive.

Priority

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

Since the instant application claims the benefit under 35 USC § 119(e) of Provisional application 60/484,685 filed July 3, 2003 and Provisional application 60/514,374 filed October 24, 2003, the

disclosures in both provisional applications were reviewed because of the possibility of intervening art. It was found that Provisional application 60/484,685 and Provisional application 60/514,374 both fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. See, for example, the definition of variables R^{6a}-R^{9a} in Provisional application 60/484,685 {i.e., variables do not form a ring} and the definition of variable R^1 in Provisional application 60/514,374. Therefore, the instant claimed invention can only rely on the filing date of 371 application, PCT/GB04/02824, which is July 5, 2004. Therefore, the following rejection applies.

Claim Rejections - 35 USC § 102

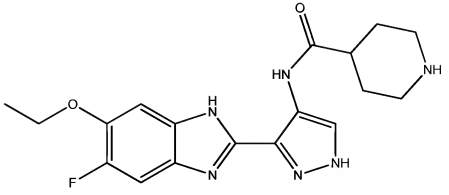
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 72, 74, 78, 80, 81 and 96 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards et al. {WO 2003/035065}.

Edwards et al. disclose, for instance, the compound on page 210, line 4 (reproduced below),

piperidine-4-carboxylic acid [3-(6-ethoxy-5-fluoro-1H-benzimidazol-2-yl)-1H-pyrazol-4-yl]amide



which is embraced by the instant claimed invention of formula (IV) when R^{6a} and R^{8a} are each hydrogen; R^{9a} is halogen {i.e., F}; R^{7a} is alkoxy {i.e., a group R^a-R^b; R^a is O; and R^b is a hydrocarbyl group}; A is C=O and R^{1a} is piperidinyl {i.e., a six-membered C-linked saturated heterocyclic group containing nitrogen

four-membered, six-membered and seven-membered monocyclic C-linked saturated heterocyclic groups containing up to three heteroatoms selected from nitrogen, oxygen and sulphur, the heterocyclic groups being optionally substituted by one to three substituents R^{10c} provided that when the heterocyclic group has six ring members and contains only one heteroatom which is oxygen, at least one substituent R^{10c} is present;

}.

Also see instant claim 81 and in Edwards et al., for instance, compound A6-B39 and compound A6-B40 on page 114; compound A7-B39 and compound A7-B40 on page 115; compound A91-B39 and compound A91-B40 on page 183; compound A92-B39 and compound A92-B40 on page 183; compound A93-B39 and compound A93-B40 on page 184; etc. Note the definitions of the "A" component is found in Table 1 on pages 94-99 and the definitions of the "B" component is found in Table 2, pages 99-110, of Edwards

et al. Therefore, Edwards et al. anticipate the instant claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 72-85, 96 and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. {WO 2003/035065}.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicant claims 2-(pyrazol-3-yl)benzimidazole compounds. **Edwards et al.** (see entire document; particularly pages 4-9, 26-29, 42-59, 94-199 and 245-

247; and especially the compound on page 210, line 4; the compound on page 203, line 35; compound A6-B39 and compound A6-B40 on page 114; compound A7-B39 and compound A7-B40 on page 115; compound A91-B39 and compound A91-B40 on page 183; compound A92-B39 and compound A92-B40 on page 183; compound A93-B39 and compound A93-B40 on page 184; and Compound 248(f) on page 421) teach 2-(pyrazol-3-yl)benzimidazole compounds that are either structurally the same as (see above 102 rejection) or structurally similar to the instant claimed compounds.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between some of the compounds of the prior art and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The indiscriminate selection of "some" among "many" is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (C.C.P.A. 1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., protein kinase inhibitors).

One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating, for example, asthma and cancers. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

Response to Arguments

Applicant's arguments filed March 25, 2010 have been fully considered but they are not persuasive.

Applicant argues that Compound 248(f) of Edwards et al. is outside the scope of Applicant's claims.

In response, it is agreed that Compound 248(f) of Edwards et al. is outside the scope of Applicant's instant claimed invention and therefore, would not anticipate the instant claimed invention. However, it is well established that consideration of a reference is not limited to the preferred embodiments or working examples, but extends to the entire disclosure for what it fairly teaches, when viewed in light of the admitted knowledge in the art, to person of ordinary skill in the art. *In re Boe*, 148 USPQ 507, 510 (CCPA 1966). Further, the compound on page 210, line 4, of Edwards et al., and many others (some of which are cited above under the 35 USC 102 rejection) are embraced by the instant claimed invention and therefore, anticipate the instant claimed invention.

Applicant argues decisions and interpretations made by another examiner in the corresponding US application

to Edwards et al. In response, considerations and determinations of patentability of claims in another application has no relevancy in the consideration and determination of patentability of claims in the instant application. See the rationale given in *In re Greider et al.*, 54 U.S.P.Q. 139 (CCPA 1942). Therefore, Applicant's argument is not persuasive.

Applicant argues that Edwards et al. teach a very large genus of compounds. In response, although the Edwards et al. teach a large genus of compounds, Edwards et al. disclose species which anticipate the instant claimed invention (see above 102 rejection) or make obvious other compounds instantly claimed. Therefore, Applicant's argument is not persuasive.

Applicant argues the comparative data disclosed in the instant specification on pages 260-262. Applicant also argues that the compounds of Edwards et al. inhibit a different family of kinases.

All of Applicant's arguments have been considered but have not been found persuasive. The comparison data in the instant specification has been considered but has not been found persuasive for the reasons stated above. Further, there is no requirement that the prior art must suggest that the claimed product will have the same or similar utility as that discovered by applicant in order to support a legal conclusion of obviousness. *In re Dillon*, 16 U.S.P.Q. 2d 1897, 1904 (Fed. Cir. 1990). However, Edwards et al. teach that their compounds are useful in treating, for instance, cancers and tumors (page 244, lines 1-16 and 29-30) and the instant specification discloses that the instant claimed compounds are useful in treating cancers (page 100, lines 14-17). Hence, Edwards et al. teach treating some of the same diseases/disorders that Applicant has disclosed in the instant specification. The rejection is deemed proper and therefore, the rejection is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:00 am to 2:30 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

/Laura L. Stockton/
Laura L. Stockton, Ph.D.
Primary Examiner, Art Unit 1626
Work Group 1620
Technology Center 1600

June 16, 2010